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AstraZeneca UK Limited, Kudos Pharmaceuticals Limited,  
The University of Sheffield, and MSD International Business GmbH*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA PHARMACEUTICALS  
LP, ASTRAZENECA UK LIMITED,  
KUDOS PHARMACEUTICALS LIMITED,  
THE UNIVERSITY OF SHEFFIELD, and  
MSD INTERNATIONAL BUSINESS  
GMBH,

*Plaintiffs,*

v.

Honorable Robert Kirsch, U.S.D.J.  
Civil Action No. 23 CV 796 (RK)(TJB)

NATCO PHARMA LIMITED and NATCO  
PHARMA INC.,

*Defendants.*

ASTRAZENECA PHARMACEUTICALS  
LP, ASTRAZENECA UK LIMITED,  
KUDOS PHARMACEUTICALS LIMITED,  
THE UNIVERSITY OF SHEFFIELD, and  
MSD INTERNATIONAL BUSINESS  
GMBH,

*Plaintiffs,*

v.

SANDOZ INC.,

*Defendant.*

Honorable Robert Kirsch, U.S.D.J.  
Civil Action No. 24 CV 641 (RK)(TJB)

**ANSWER TO COUNTERCLAIMS OF SANDOZ INC.**

Plaintiffs and Counterclaim Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH, (collectively, “Plaintiffs”), by their attorneys, hereby answer the counterclaims of Defendant and Counterclaim Plaintiff Sandoz Inc. (“Sandoz”).

**NATURE OF THE ACTION**

1. The allegations of Paragraph 1 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that Sandoz seeks approval of its Abbreviated New Drug Application (“ANDA”) No. 217936 and to manufacture and sell the products described therein.

**PARTIES**

2. On information and belief, Plaintiffs admit the allegations of Paragraph 2.

3. Plaintiffs admit the allegations of Paragraph 3.

4. Plaintiffs admit the allegations of Paragraph 4.

5. Plaintiffs admit the allegations of Paragraph 5.

6. Plaintiffs admit the allegations of Paragraph 6.

7. Plaintiffs admit the allegations of Paragraph 7.

8. Plaintiffs admit that Kudos Pharmaceuticals Limited is the assignee of U.S. Patent No. 7,449,464 (the “’464 Patent”), U.S. Patent No. 8,475,842 (the “’842 Patent”), and U.S. Patent No. 11,633,396 (“’396 Patent”). Plaintiffs deny that Kudos Pharmaceuticals Limited is the assignee of U.S. Patent No. 8,859,562 (the “’562 Patent”). The University of Sheffield is the assignee of the ’562 Patent.

9. Plaintiffs admit the allegations of Paragraph 9.

10. Plaintiffs admit the allegations of Paragraph 10.

### **JURISDICTION AND VENUE**

11. The allegations of Paragraph 11 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that Sandoz has asserted Counterclaims under the Declaratory Judgment Act.

12. The allegations of Paragraph 12 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this Court has subject matter jurisdiction over this action.

13. The allegations of Paragraph 13 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this Court has personal jurisdiction over Plaintiffs.

14. The allegations of Paragraph 14 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that venue is proper in this Court.

### **BACKGROUND**

15. Plaintiffs admit the allegations of Paragraph 15.

16. The allegations of Paragraph 16 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the Patents-in-Suit.

### **PATENTS-IN-SUIT**

17. Plaintiffs admit that the PTO issued the '464 Patent on November 11, 2008. A true and correct copy of the '464 Patent is attached to the Complaint as Exhibit A (ECF No. 1-1), which shows its issuance date, title, and inventors. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

18. Plaintiffs admit that the PTO issued the '842 Patent on July 2, 2013. A true and correct copy of the '842 Patent is attached to the Complaint as Exhibit B (ECF No. 1-2), which shows its issuance date, title, and inventors. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

19. Plaintiffs admit that the PTO issued the '396 Patent on April 25, 2023. A true and correct copy of the '396 Patent is attached to the Complaint as Exhibit C (ECF No. 1-3), which shows its issuance date, title, and inventors. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

20. Plaintiffs admit that the PTO issued the '562 Patent on October 14, 2014. A true and correct copy of the '562 Patent is attached to the Complaint as Exhibit D (ECF No. 1-4), which shows its issuance date, title, and inventors. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

21. The allegations of Paragraph 21 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that they have the right to maintain an infringement suit against Sandoz prior to the expiration of the Patents-in-Suit. Plaintiffs do not have enough information to admit or deny whether they would have the right to maintain an infringement suit against an unnamed third party before the expiration of the Patents-in-Suit.

22. Plaintiffs admit that the Patents-in-Suit are published in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), in connection with NDA No. 208558.

23. The allegations of Paragraph 23 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that they have the right to maintain an infringement suit against Sandoz prior to the expiration of the Patents-in-Suit. Plaintiffs do not have enough information to admit or deny whether they would have the right to maintain an infringement suit against an unnamed third party before the expiration of the Patents-in-Suit.

**SANDOZ'S ANDA NO. 217936**

24. On information and belief, Plaintiffs admit the allegations of Paragraph 24.

25. Plaintiffs admit they received a letter, dated December 29, 2023, wherein Sandoz notified Plaintiffs that Sandoz had submitted to the FDA an ANDA, No. 217936, to obtain

approval to market Sandoz's ANDA Product. Plaintiffs further admit, on information and belief, that Sandoz, as part of its ANDA No. 217936, filed Paragraph IV Certifications with respect to the Patents-in-Suit. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

26. Plaintiffs admit that Sandoz's notice letter included an Offer of Confidential Access to its ANDA Product. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

27. The allegations of Paragraph 27 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that Paragraph 27 accurately sets forth the language of 21 U.S.C. § 355(j)(5)(C)(i)(III).

28. The allegations of Paragraph 28 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that Sandoz attached to its Notice Letter a statement containing arguments about its Paragraph IV Certifications.

29. The allegations of Paragraph 29 set forth legal conclusions to which no response is required.

30. Plaintiffs admit that they sent a letter, dated January 11, 2024, explaining the deficiencies in Sandoz's Offer of Confidential Access. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

31. Plaintiffs admit they received a letter from Sandoz, dated January 19, 2024, and that Sandoz's counsel spoke with Plaintiffs' counsel on January 25, 2024, to discuss the Offer of Confidential Access. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

32. Plaintiffs admit that Plaintiffs filed the Complaint in this action on February 2, 2024. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

**COUNT I**  
**(Declaratory Judgment of Non-Infringement of the '464 Patent)**

33. In Paragraph 33, Sandoz purports to repeat and incorporate by reference the allegations set forth in Paragraphs 1-32 of its Counterclaims. Plaintiffs therefore reallege and incorporate by reference their response to Paragraphs 1-32 as though set forth herein.

34. The allegations of Paragraph 34 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '464 Patent.

35. Plaintiffs admit Sandoz seeks a declaratory judgment that it will not infringe the '464 Patent. Plaintiffs deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

36. The allegations of Paragraph 36 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny that Sandoz is not liable for infringement of the '464 Patent. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

37. Plaintiffs admit that Sandoz's notice letter purports to reserve the right to assert additional grounds of non-infringement, invalidity, and unenforceability as to the '464 Patent. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

38. The allegations of Paragraph 38 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and

justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '464 Patent.

39. Plaintiffs deny that Sandoz is not liable for infringement of the '464 Patent and further deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

**COUNT II**  
**(Declaratory Judgment of Invalidity of the '464 Patent)**

40. In Paragraph 40, Sandoz purports to repeat and incorporate by reference the allegations set forth in Paragraphs 1-39 of its Counterclaims. Plaintiffs therefore reallege and incorporate by reference their response to Paragraphs 1-39 as though set forth herein.

41. The allegations of Paragraph 41 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '464 Patent.

42. The allegations of Paragraph 42 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny that the '464 Patent is invalid. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

43. Plaintiffs deny that the '464 Patent is invalid and deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.



**COUNT III**  
**(Declaratory Judgment of Non-Infringement of the '842 Patent)**

44. In Paragraph 44, Sandoz purports to repeat and incorporate by reference the allegations set forth in Paragraphs 1-43 of its Counterclaims. Plaintiffs therefore reallege and incorporate by reference their response to Paragraphs 1-43 as though set forth herein.

45. The allegations of Paragraph 45 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '842 Patent.

46. Plaintiffs admit Sandoz seeks a declaratory judgment that it will not infringe the '842 Patent. Plaintiffs deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

47. The allegations of Paragraph 47 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny that Sandoz is not liable for infringement of the '842 Patent. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

48. Plaintiffs admit that Sandoz's notice letter purports to reserve the right to assert additional grounds of non-infringement, invalidity, and unenforceability as to the '842 Patent. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

49. The allegations of Paragraph 49 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding

Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '842 Patent.

50. Plaintiffs deny that Sandoz is not liable for infringement of the '842 Patent and further deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

**COUNT IV**  
**(Declaratory Judgment of Invalidity of the '842 Patent)**

51. In Paragraph 51, Sandoz purports to repeat and incorporate by reference the allegations set forth in Paragraphs 1-50 of its Counterclaims. Plaintiffs therefore reallege and incorporate by reference their response to Paragraphs 1-50 as though set forth herein.

52. The allegations of Paragraph 52 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '842 Patent.

53. The allegations of Paragraph 53 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny that the '842 Patent is invalid. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

54. Plaintiffs deny that the '842 Patent is invalid and deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

**COUNT V**  
**(Declaratory Judgment of Non-Infringement of the '396 Patent)**

55. In Paragraph 55, Sandoz purports to repeat and incorporate by reference the allegations set forth in Paragraphs 1-54 of its Counterclaims. Plaintiffs therefore reallege and incorporate by reference their response to Paragraphs 1-54 as though set forth herein.

56. The allegations of Paragraph 56 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '396 Patent.

57. Plaintiffs admit Sandoz seeks a declaratory judgment that it will not infringe the '396 Patent. Plaintiffs deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

58. The allegations in Paragraph 58 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny that Sandoz is not liable for infringement of the '396 Patent. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

59. Plaintiffs admit that Sandoz's notice letter purports to reserve the right to assert additional grounds of non-infringement, invalidity, and unenforceability as to the '396 Patent. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

60. The allegations of Paragraph 60 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding

Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '396 Patent.

61. Plaintiffs deny that Sandoz is not liable for infringement of the '396 Patent and further deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

**COUNT VI**  
**(Declaratory Judgment of Invalidity of the '396 Patent)**

62. In Paragraph 62, Sandoz purports to repeat and incorporate by reference the allegations set forth in Paragraphs 1-61 of its Counterclaims. Plaintiffs therefore reallege and incorporate by reference their response to Paragraphs 1-61 as though set forth herein.

63. The allegations of Paragraph 63 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '396 Patent.

64. The allegations of Paragraph 64 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny that the '396 Patent is invalid. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

65. Plaintiffs deny that the '396 Patent is invalid and deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

**COUNT VII**  
**(Declaratory Judgment of Non-Infringement of the '562 Patent)**

66. In Paragraph 66, Sandoz purports to repeat and incorporate by reference the allegations set forth in Paragraphs 1-65 of its Counterclaims. Plaintiffs therefore reallege and incorporate by reference their response to Paragraphs 1-65 as though set forth herein.

67. The allegations of Paragraph 67 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '562 Patent.

68. Plaintiffs admit Sandoz seeks a declaratory judgment that it will not infringe the '562 Patent. Plaintiffs deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

69. The allegations in Paragraph 69 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny that Sandoz is not liable for infringement of the '562 Patent. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

70. Plaintiffs admit that Sandoz's notice letter purports to reserve the right to assert additional grounds of non-infringement, invalidity, and unenforceability as to the '562 Patent. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

71. The allegations of Paragraph 71 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding

Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '562 Patent.

72. Plaintiffs deny that Sandoz is not liable for infringement of the '562 Patent and further deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

**COUNT VIII**  
**(Declaratory Judgment of Invalidity of the '562 Patent)**

73. In Paragraph 73, Sandoz purports to repeat and incorporate by reference the allegations set forth in Paragraphs 1-72 of its Counterclaims. Plaintiffs therefore reallege and incorporate by reference their response to Paragraphs 1-72 as though set forth herein.

74. The allegations of Paragraph 74 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that there is an actual and justiciable controversy between Plaintiffs on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '562 Patent.

75. The allegations of Paragraph 75 set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny that the '562 Patent is invalid. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

76. Plaintiffs deny that the '562 Patent is invalid and deny that Sandoz is entitled to any of the relief it seeks. To the extent there are remaining allegations of this paragraph, Plaintiffs deny them.

**RESPONSE TO PRAYER FOR RELIEF**

The "WHEREFORE" paragraphs following Paragraph 76 state Sandoz's Prayer for Relief, to which no response is required. To the extent a response is required, Plaintiffs deny the

allegations of the “WHEREFORE” paragraphs and deny that Sandoz is entitled to any of the relief requested therein, or to any relief whatsoever.

\* \* \*

To the extent that a further answer is required to any paragraphs of Sandoz’s Counterclaims, Plaintiffs deny all further allegations. Any allegation in the Counterclaims not expressly admitted herein is hereby denied.

### **AFFIRMATIVE DEFENSES**

#### **FIRST AFFIRMATIVE DEFENSE**

Sandoz’s Counterclaims fail to allege facts sufficient to state a cause of action and fail to state a claim on which relief may be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

Sandoz’s Counterclaims have failed to state a claim upon which relief for exceptional cases under 35 U.S.C. § 285 can be granted.

#### **THIRD AFFIRMATIVE DEFENSE**

Sandoz’s Counterclaims have failed to properly plead or put Plaintiffs on fair notice of any theory or grounds upon which the Patents-in-Suit could be found to be unenforceable. Sandoz’s defense of unenforceability is therefore legally insufficient as it is no more than a rote recitation of a generally available affirmative defense without the legally required level of specificity.

\* \* \*

Plaintiffs reserve the right to supplement and/or amend these affirmative defenses as may become available or apparent during discovery proceedings.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request the following relief:

- a) An order dismissing each of Sandoz's counterclaims, with prejudice, and denying all relief sought by Sandoz;
- b) A judgment that each of the Patents-in-Suit has been infringed under 35 U.S.C. § 271(e)(2) by Sandoz's submission to the FDA of Sandoz's ANDA;
- c) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, offer for sale, sale, distribute, or import of Sandoz's ANDA Product, or any other drug product that infringes or the use of which infringes one or more of the Patents-in-Suit, be not earlier than the latest of the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;
- d) A preliminary and permanent injunction enjoining Sandoz, and all persons acting in concert with Sandoz, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the Patents-in-Suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;
- e) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Sandoz's ANDA Product, or any other drug product which is covered by or whose use is covered by one-or-more of the Patents-in-Suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents;
- f) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- g) Costs and expenses in this action; and
- h) Such further and other relief as this Court may deem just and proper.



Dated: April 19, 2024

Respectfully submitted,

/s/ Charles H. Chevalier

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AstraZeneca UK Limited, Kudos  
Pharmaceuticals Limited,  
The University of Sheffield, and  
MSD International Business GmbH*

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of Plaintiffs' **ANSWER TO COUNTERCLAIMS OF SANDOZ INC.** was caused to be served this 19<sup>th</sup> day of April through the Court's electronic filing system and electronic mail upon the following:

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Date: June 12, 2023

/s/ Charles H. Chevalier  
Charles H. Chevalier